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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/904,568	07/16/2001	Johanne Tremblay	004780.00001	3854

22907 7590 07/17/2002

BANNER & WITCOFF  
1001 G STREET N W  
SUITE 1100  
WASHINGTON, DC 20001

EXAMINER

WANG, ANDREW J

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 07/17/2002 11

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/904,568	<b>Applicant(s)</b> TREMBLAY ET AL.	
	<b>Examiner</b> Andrew Wang	<b>Art Unit</b> 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All   b) ☐ Some \* c) ☐ None of:  
1. ☒ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____   |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>5</u> | 6) <input type="checkbox"/> Other:  |

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### DETAILED ACTION

1. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-6, 11, 14-16, and 19 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claimed nucleic acid sequences read on products of nature since the hand of man is not apparent in the claim language. Inserting --isolated-- before "nucleic acid" in claim 1, for example, would be remedial.

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3-5, 7-14, and 16-23 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The invention of the above claims is drawn to any nucleotide sequence encoding isolatable from a mammal parathyroid whose expression is regulated by extracellular calcium ions, probes specifically hybridizable with SEQ ID NO: 1 and 3, and vectors and compositions comprising said nucleic acid sequences.

The specification teaches the isolation of two polynucleotide sequences from rat and human parathyroid glands that were regulated by calcium ion concentration.

The specification does not teach any other sequences, other than SEQ ID NO: 1 and 3, that are regulated by extracellular calcium ion concentration. Although the specification generically discusses how to isolate other sequences from parathyroid glands, no description of any type of nucleotide sequences is provided that would allow the skilled artisan to readily envision what polynucleotide sequences are being claimed. Without the requisite description in the specification as to what nucleotide sequences are regulated by extracellular calcium, the skilled artisan would not recognize that the applicants were in possession of the claimed polynucleotides since the specification does not even teach what sequences would be regulated by extracellular calcium other than SEQ ID NO: 1 and 3.

Moreover, the specification does not disclose any sequences within SEQ ID NO: 1 and 3 that would allow for specific hybridization of probes. Without a specific description of the contemplated hybridization sequences, the skilled artisan would not envision any sequences that would specifically hybridize with SEQ ID NO: 1 and 3.

Thus, applicants disclosure combined with what was known in the art is not sufficient to describe the claimed genus of polynucleotides that is regulated by extracellular calcium as well as probes which hybridizes specifically with SEQ ID NO: 1 and 3.

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3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-6 and 11-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2-6, 12, and 13 are unclear since applicants use the indefinite article "A". Replacing "A" with --The-- would be remedial.

Claims 11-13 are unclear since the metes and bounds of the phrase "specifically hybridizes" can not be determined. Specific hybridization depends upon many conditions such as temperature, salt concentration, GC content, and oligo length, which applicants have not specifically defined. Thus, the metes and bounds of the nucleic acid probe cannot be determined since applicants have not provided the conditions for determining specific hybridization.

4. Claim 1 is objected to because of the following informalities: Claim 1 recites "isolable" that appears to be a mis-spelling of --isolatable--. Appropriate correction is required.

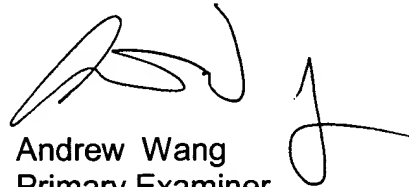
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew Wang whose telephone number is 703-306-3217. The examiner can normally be reached on Monday thru Thursday, 6:30 a.m.-5:00 p.m.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on 703-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

AJW  
July 15, 2002



Andrew Wang  
Primary Examiner  
Art Unit 1635